



10/31/2019

Dear Requestor,

The attached record(s) are being provided by the Office of Regulatory Affairs (ORA), Division of Information Disclosure Policy (DIDP) – Office of Criminal Investigations (OCI), in response to your request 2019-9240, for records from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA) regarding:

FDA files on Dr. Jeff Bradstreet (deceased)

Your request is granted in part.

After a thorough review of the responsive records, we have determined that portions of the documents are exempt from disclosure under FOIA exemptions (b)(4), (b)(5), (b)(6), and (b)(7) of the FOIA 5 U.S.C. § 552, as amended and delineated below:

- Exemption (b)(4) permits the withholding of “trade secrets” (TS) and “commercial confidential information” (CCI). Disclosure of this information would impair the government’s ability to obtain necessary information in the future and cause substantial harm to the competitive position of the person from whom the information was obtained. Under the balancing test of this exemption, we are withholding all proprietary information identified as TS and CCI.
- Exemption (b)(5) permits the withholding of inter-agency or intra-agency communications records which are part of the deliberative process and pre-decisional. Disclosure of such material could inhibit the open and candid expression of opinions and diminish the quality of the decision-making process.
- Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. In this case, it was determined that there is no countervailing public interest qualifying under the standard set forth, under exemption (b)(6), to release the personal identifying information of certain third parties.
- Exemption (b)(7) protects from disclosure "records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information (A) could reasonably be expected to interfere with enforcement proceedings, (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy, (E) would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could



reasonably be expected to risk circumvention of the law, or (F) could reasonably be expected to endanger the life or physical safety of any individual.

OCI considers your request closed. If you have any questions about this response, you may contact Fran Seiner at 301-821-2089.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response to:

Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
Email: FOIARequest@PSC.hhs.gov

Please clearly mark both the envelope and your letter or email "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Fran Seiner. You may also contact the FDA Public Liaison for assistance at:

Office of the Executive Secretariat
U.S. Food & Drug Administration
5630 Fishers Lane
Room 1050
Rockville, MD 20857
Email: FDAFOIA@fda.hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is as follows:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001



Phone: 202-741-5770
Toll-Free: 877-684-6448
Email: ogis@nara.gov

Please do not submit payment until you receive an invoice. The following charges for this request to date may be included in a monthly invoice:

Search = \$11.50; Review = \$34.50; Administrative Fee = \$5.75: Total = \$51.75

Sincerely,

Frances M. Seiner
OCI, FOIA Officer